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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,031 03/10/99 LONGACRE-ANDRE

S 0660-0139-0X

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EXAMINER
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ART UNIT	PAPER NUMBER
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1641  
DATE MAILED: 09/10/01

*23*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/125,031

Applicant(s)  
LONGACRE-ANDRE et al.

Examiner  
James L. Grun, Ph.D.

Art Unit  
1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8 Aug 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 46-53, 55-63, and 65-68 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 68 is/are allowed.
- 6) ☒ Claim(s) 46-53, 55-63, and 65-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 August 2001 is acknowledged and has been entered.

Claims 65-68 are newly added. Claims 54 and 64 have been cancelled. Claims 46-53, 55-63, and 65-68 remain in the case. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. When formal drawings are submitted, the draftsman will perform a review. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

Claims 46-50, 53, 56-63, and 65-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particular constructs as found in the deposited viruses given CNCM registration numbers I-1659, I-1660, I-1661, I-1662, and I-1663, does not

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reasonably provide description or enablement for an invention of the scope as instantly claimed wherein those N-terminal *Plasmodium* MSP-1 signal peptide-encoding sequences critical or essential to the practice of the invention are not included in the claims. The polynucleotide constructs appear to require nucleic acids encoding the N-terminal signal sequence of a *Plasmodium* MSP-1 protein for use in the invention and for expression by recombinant baculovirus in Sf9 cells (Longacre et al., Mol. Biochem. Parasitol. 64:191, 1994; see page 201, column 2). The function of no signal sequence other than that of the *Plasmodium* MSP-1 protein is taught by applicant in the invention and the ability of another signal sequence to result in appropriate expression of the protein would seem unknown and unpredictable. Thus, one would have no assurance of the ability to make and use constructs which function in the invention in the absence of these required sequences. The specification does not describe, and thus, does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use, the invention commensurate in scope with these claims.

Applicant's arguments filed 08 August 2001 have been fully considered but they are not deemed to be persuasive. Applicant urges that the instant amendments to recite a signal peptide from an MSP-1 protein or to recite a signal sequence from *Plasmodium vivax* obviate the rejection based on the above reasons. This is not found persuasive for the reasons of record and as set forth above because the critical N-terminal signal peptide-encoding sequence of a *Plasmodium* MSP-1 protein is not specifically recited.

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Claims 46-53, 55-63, and 65-67 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 46-53, "MSP-1" and the interrelationships of the components are not clear. The following is suggested: --fragment of a *Plasmodium falciparum* merozoite surface protein 1 (MSP-1) protein, wherein said synthetic polynucleotide has a GC content of 40 to 60%, and a polynucleotide encoding a signal peptide of a *Plasmodium* MSP-1 protein--.

In claims 48-50, 58-60, and 66-67, it is suggested that --glycosylphosphatidylinositol anchor coding sequence-- might be intended.

In claim 55, "vector..." is vague in the absence of recitation of deposit accession/registration number(s) to clearly identify that(those) encompassed by the claims.

In claims 56-63, "MSP-1" is not clear. The following is suggested: --fragment of a *Plasmodium falciparum* merozoite surface protein 1 (MSP-1) polypeptide, wherein said polynucleotide has a total GC content of 40 to 60%--.

In claim 59, "said glycosylphosphatidylinositol coding sequence" lacks antecedent basis. It is suggested that the claim was intended to depend upon claim 58.

In claims 65-67, "MSP-1" and the interrelationships of the components are not clear. The following is suggested: --fragment of a *Plasmodium falciparum* merozoite surface protein 1 (MSP-1) protein, having a GC content of between 40 to 60%, and a polynucleotide encoding a signal sequence of a *Plasmodium vivax* MSP-1 protein--.

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Applicant's arguments filed 08 August 2001 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's argument to the contrary, claim 52 depends from claim 51, not claim 46.

Claims 56, 58, and 61 are rejected under 35 U.S.C. § 102(b) as being anticipated by Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994) in light of the instant disclosure, for reasons of record.

Applicant's arguments filed 08 August 2001 have been fully considered but they are not deemed to be persuasive.

Applicant urges that Longacre et al do not disclose a polynucleotide having a GC content of 40-60% because the native encoding sequence of the *Plasmodium falciparum* MSP-1 has only 33% GC and the MSP-1 proteins of *P. falciparum* and *Plasmodium vivax* are different. These are not found persuasive because the arguments are drawn to the sequence of the *P. falciparum* MSP-1 encoding sequence, not to the *P. vivax* MSP-1 encoding sequence of the reference and rejection, and because the instantly rejected claims are not limited to the *P. falciparum* MSP-1 encoding sequence.

Claims 46, 48, 55, 56, 58, 61, and 65-66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Chappel et al (Mol. Biochem. Parasitol. 60:303, 1993), Miller et al (Mol. Biochem. Parasitol. 59:1, 1993), and Longacre et al (Mol. Biochem.

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Parasitol. 64:191, 1994), for reasons of record in the prior rejection of the similar subject matter of claims 46, 48, 51, 54-56, 58, and 61. In addition to the reasons of record, it would have been further obvious to one of ordinary skill in the art at the time the instant invention was made to have applied the teachings of the references of Chappel et al, Miller et al, and Longacre et al to the cloning and expression of the encoding sequences for the C-terminal p19 fragment of the MSP-1 protein of any *Plasmodium* species of interest in a baculovirus vector in insect cells. One would have had a reasonable expectation of success guided by and in view of the successful production of a variety of like soluble and/or anchored MSP-1 fragments with baculovirus constructs as taught in Chappel et al or Longacre et al.

Applicant's arguments filed 08 August 2001 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the declaration of Dr. Longacre-Andre under 37 CFR § 1.132, filed 03 August 2000, provides sufficient evidence of unobvious and unpredictable advantages to overcome the rejection. This is not found persuasive as the showing in the declaration is incommensurate in scope with the invention as claimed in the instantly rejected claims.

Applicant urges that the references do not teach or provide motivation for altering the GC content of the nucleotide sequence of the *P. falciparum* MSP-1 encoding sequence. This is not found persuasive because all of the rejected claims are not limited to the *P. falciparum* MSP-1 encoding sequence, polynucleotides encoding the MSP-1 proteins of a variety of plasmodial parasites fall, without modification, into the recited range, and, as set forth above, to construct

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vectors for the reasonably expected successful expression of the proteins would have been obvious guided by the teachings of the references. Further, as set forth, one would have expected many polynucleotides of the genus specifically encoding the known sequence of the *P. falciparum* MSP-1 protein p19 fragment to function in such vectors as taught in the references.


Claim 68 is currently allowable.

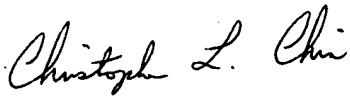
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

  
James L. Grun, Ph.D.  
September 7, 2001

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641